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| 09/920,310      | 08/01/2001  | Yves Claude Nicolau  | GMV-005.01          | 5052             |

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EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/920,310

Applicant(s)

NICOLAU ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2004 and 21 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☒ Claim(s) 1-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12 December 2002 → 1/25/02
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-33 are currently pending in the instant application. Claims 30-33 are withdrawn from consideration as being for non-elected subject matter and claims 1-29 are objected and rejected.

#### ***Election/Restrictions***

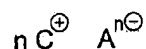
Applicant's election with traverse of Group I, claims 1-29 and the further election of the compound wherein the aliphatic ammonium cation is cyclohexylammonium cation with  $n=11$ , and a sodium cation with  $n=1$ , and the anionic ligand for a mammalian cellular receptor is inositol hexaphosphate in the reply filed on 25 February 2004 is acknowledged. The traversal is on the ground(s) that the examination of groups II-IV along with the elected group I would not place an undue burden on the examiner. This is not found persuasive because The inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter, which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner. In regards to applicants statement that the election of a specific compound is made herein solely for search purpose, the examiner points out page 4 of the restriction requirement which states that upon the election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound and examination will then proceed on the elected

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compound and the entire scope of the invention encompassing the elected compound as determined by the Office. Therefore, based upon the election of the compound wherein the aliphatic ammonium cation is cyclohexylammonium cation with  $n=11$ , and a sodium cation with  $n=1$ , and the anionic ligand for a mammalian cellular receptor is inositol hexaphosphate;

**The elected invention for search and examination is:**

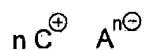
The compositions comprising the compounds represented by the structure 1:



**1**

Wherein  $C^+$  represents independently for each occurrence a cyclohexylammonium cation, an alkali metal cation, or an alkaline earth cation; provided that at least one instant of  $C^+$  represents cyclohexylammonium cation; and  $A^-$  represents inositol hexaphosphate; and  $n$  is an integer in the range of 1 to 12 inclusively.

And the compounds represented by the structure 1:



**1**

Wherein  $C^+$  represents independently for each occurrence a cyclohexylammonium cation, an alkali metal cation, or an alkaline earth cation; provided that at least one instant of  $C^+$  represents cyclohexylammonium cation; and  $A^-$  represents inositol hexaphosphate; and  $n$  is an integer in the range of 1 to 12 inclusively.

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The remaining subject matter of claims 1-29 that is not drawn to the above elected invention and the subject matter of claims 30-33 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining compounds which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims are, for example, the compounds wherein the ligand for a mammalian cellular receptor is 2,3-diphosphoglyceric acid..

The above mentioned withdrawn compounds which are withdrawn from consideration as being for nonelected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds contain differ from those of the elected invention and are chemically recognized to differ in structure and function. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefor withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,610,702. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 of US Patent No. 6,610,702 anticipates the instantly claimed elected invention of claims 1-29 since claim 7 claims the compound of claim 1, wherein  $n\text{C}$  of  $n\text{C}^{\oplus} \text{A}^{n\ominus}$  represents undeca-cyclohexylammonium, and wherein claim 1

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states that An- is a conjugate base of inositol hexaphosphate, wherein n equals the number of cations comprised by nC+. Therefore, claim 7 is drawn solely to the compound ICP4 (Figure 4) of US Patent No. 6,610,702 which anticipates applicants instant composition claims which must only comprise a salt complex as found in the US Patent claim 7 and which anticipates applicants instant compound claims since the compound ICP4 is fully encompassed by applicants instant elected invention.

Claims 1-29 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 7 of US Patent No. 6,610,702. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

***Determining the scope and content of the conflicting claims of US Patent 6,610,702***

Claims 1-3 and 7 of US Patent NO. 6, 610,702 disclose the compounds and compositions of the formula 1:



1

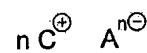
wherein An- is a conjugate base of inositol hexaphosphate, wherein n equals the number of cations comprised by nC+ and nC+ is, for example nona-cyclohexylammonium-tri-sodium (within applicants instant invention), his-dicyclohexylammonium-deca-sodium and undeca-cyclohexylammonium (within applicants instant invention) which overlaps with applicants instant elected invention of claims 1-29. Claims 2-3 further limit the compound of claim 1 to include, for example, nona-cyclohexylammonium-tri-sodium and undeca-cyclohexylammonium. Claim 7 anticipates applicants instant claims 1-29 as discussed above.

***Ascertaining the differences between the conflicting patent claims and applicants instant elected invention of claims 1-29***

The difference between the conflicting patent claims of 1-3 and 7 and applicants instant elected invention of claims 1-29 is that claims 1 overlaps with applicants instant elected invention, claims 2-3 disclose preferences towards applicants instant elected invention, however, these claims still overlap with applicants instant elected invention of claims 1-29. Claim 7, as discussed above, anticipates applicants instant elected invention of claims 1-29.

***Resolving the level of ordinary skill in the art***

However, it would have been obvious to one of ordinary skill in the art to prepare the compounds and composition of applicants instant elected invention of claims 1-29 since the US Patent No. 6, 610, 702 discloses compounds of the formula



1

wherein the definitions of nC and A overlap with applicants instant elected invention since US Patent NO. 6,610,702 discloses that An<sup>-</sup> is a conjugate base of inositol hexaphosphate and discloses preferences towards the nC as nona-cyclohexylammonium –tri-sodium (see further limiting claims 2 and 3) and undeca-cyclohexylammonium (see claim 7) which anticipates applicants instant elected invention of claims 1-29 and would provide motivation to one of ordinary skill in the art to prepare the compounds as instantly found in applicants elected invention of claims 1-29. Therefore, the instant claims 1-29 are rejected over claims 1-3 and 7 under the judicially created doctrine of obviousness-type double patenting.



### ***Claim Objections***

Claims 1-29 are objected to as containing non-elected subject matter. Claims 1-29 rewritten to include only the subject matter of the elected invention as identified *supra* and free of the double patenting rejection would appear allowable over the prior art of record.

The closest prior art of record is Adachi et al. (BX reference on 1449). Adachi et al. discloses controlled aggregation of deoxyhemoglobing S, discloses inositol hexaphosphate and discloses the pentacyclohexylammonium salt of diphosphoglyceric acid. However, the reference fails to disclose a compound or composition within applicants instant elected invention wherein the aliphatic ammonium cation is cyclohexylammonium cation and the anionic ligand for mammalian cellular receptor is inositol hexaphosphate and also fails to provide motivation to prepare a compound or composition of the instant elected invention.

### **Conclusion**


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

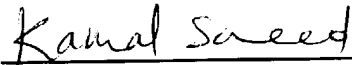
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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